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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/603,094	06/25/2003	Don J. Diamond	1954-410	7356
6449	7590	09/19/2006		
ROTHWELL, FIGG, ERNST & MANBECK, P.C. 1425 K STREET, N.W. SUITE 800 WASHINGTON, DC 20005				
			EXAMINER HUMPHREY, LOUISE WANG ZHIYING	
			ART UNIT 1648	PAPER NUMBER

DATE MAILED: 09/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/603,094	DIAMOND, DON J.	
	Examiner	Art Unit	
	Louise Humphrey, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 3, 4 and 12-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2 and 5-11 is/are rejected.
- 7) ☒ Claim(s) 5 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 June 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/8/04, 6/9/04, 4/20/05</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

The Office acknowledges the receipt of Applicant's election and Amendment, filed on 5 September 2006.

Election/Restriction

Applicant elects Group I, claims 1-9, and the species of PADRE, with traverse. The traversal is on the ground that claims 10-13 are omitted in the prior Office Action. Examiner hereby adds claims 10-13 into to Group I. The restriction between the product and the method is maintained. The requirement is still deemed proper and is therefore made FINAL.

Claims 1-14 are pending. Claims 3, 4, 12-14 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 05 September 2006. Claims 1, 2, and 5-11 are examined

Sequence Compliance

Claim 5 is objected to for failing to adhere to the requirements of the sequence rules. Applicant must append SEQ ID Nos. to all mentions of specific sequences in the specification and the claims, specifically, pp65₁₃₋₂₄, pp65₁₈₆₋₁₉₆, pp65₁₈₈₋₁₉₅, pp65₂₆₅₋₂₇₅, pp65₃₆₃₋₃₇₃, pp65₃₆₉₋₃₇₉, pp65₃₆₇₋₃₇₉, and pp65₄₁₇₋₄₂₆. See 37 CFR § 1.821(d). Full compliance is required in response to this Office Action. A reply that fails to comply will be considered to be non-responsive and may result in abandonment of this application.

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Information Disclosure Statement

Initialed and dated copies of Applicant's IDS form 1449, filed on 08 March 2004, 09 June 2004, and 20 April 2005, are attached to the instant Office action.

Claim Rejections - 35 USC § 112, 2nd ¶

The following is a quotation of the second paragraph of 35 U.S.C. §112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 8 is rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 8 recites the limitation "said DNA adjuvant" in the second line. There is insufficient antecedent basis for this limitation in the claim.

Clarification and/or correction are required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –
(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 5, 6, and 9-11 are rejected under 35 U.S.C. §102(e) as being anticipated by Khanna *et al.* (US 2005/0019344 A1).

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The instant claims are directed to a cytomegalovirus (CMV) vaccine, which comprises a fusion peptide composed of a T helper epitope fused to a CMV CTL epitope peptide.

Khanna *et al.* teach a vaccine comprising HCMV pp65-specific CTL epitope, NLVPMVATV, which matches SEQ ID NO:1 in the instant application, linked to the pan-HLA-DR T-helper epitope (column 2, ¶38, column 3, ¶42, ¶47). Khanna *et al.* further teach a prophylactic or therapeutic vaccine composition for eliciting a cellular immune response in a human subject against HCMV, said composition comprising an immunologically active peptide of the invention in combination with a pharmaceutically acceptable carrier, excipient, diluent and/or an adjuvant (column 4, ¶79).

Thus, the instant invention is anticipated by Khanna *et al.*

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7 and 8 are rejected under 35 U.S.C. §103(a) as being unpatentable over Khanna *et al.*, *supra*, in view of Krieg *et al.* (WO122972, 30 Apr 2001).

The instant invention further comprises a DNA adjuvant.

The relevance of Khanna *et al.* is set forth above. Khanna *et al.* do not disclose a DNA adjuvant.

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Krieg *et al.* describes immunostimulatory nucleic acids. Specifically, Krieg *et al.* discloses a DNA that matches the sequence of the instantly claimed SEQ ID NO:10. See page 57, SEQ ID NO:959, in Table A.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the vaccine adjuvant of Khanna *et al.* by adding DNA adjuvant as taught by Krieg *et al.* The skilled artisan would have been motivated to do so to enhance immune response. There would have been a reasonable expectation of success, given the discovery that these DNA adjuvants preferentially activate non-rodent immune cells, as taught by Krieg *et al.* Thus, the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Remarks

No claim is allowable.

Applicant is reminded that any amendment must point to a basis in the specification so as not to add new matter. See MPEP §714.02 and §2163.06.

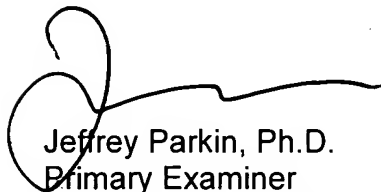
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Contact Information


Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise Humphrey, Ph.D. whose telephone number is 571-272-5543. The examiner can normally be reached on Mon-Fri, 9:30 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Jeffrey Parkin, Ph.D.
Primary Examiner
14 September 2006



9/14/06